

PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

ROMA

Centro Congressi di Confindustria

Auditorium della Tecnica 9ª Edizione

30 Settembre

1 Ottobre

2022

Valvola mitrale

TRATTAMENTO PERCUTANEO VALVE IN VALVE E VALVE IN

RING Sergio Berti







Potential conflict of interest

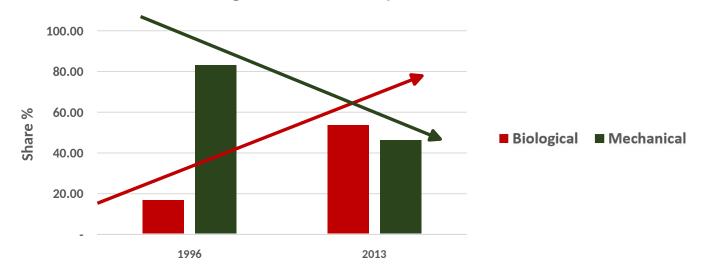
Speaker's name: Sergio Berti

- ☐ I have the following conflict of interest to report:
 - ☐ Proctor: Edwards, Boston, Abbott, J&J



Surgical mitral valve replacement: mechanical vs. biological

Use of mechanical vs. biological mitral valve prostheses¹



- Over the last 25 years, mitral valve replacement with biological prostheses has increasingly replaced mechanical prostheses.^{1,2}
- In total the incidence of reoperation is higher among patients receiving a biologic prosthesis compared to those receiving a mechanical prosthesis.

What if a reoperation becomes necessary for the patients with a biological prosthesis?

¹Goldstone et al. N Engl J Med . 2017 Nov 9;377(19):1847-1857

²Gammie et al. Ann Thorac Surg . 2009 May;87(5):1431-7; discussion 1437-9

The operative mortality risk of repeat mitral valve surgery is high

6.3%
elective
17.8%
emergent
1,973
patients
Vancouver
CA¹

12.8%96 patients
Istanbul,
Turkey²

11-15% 53 patients Texas³ 8.2%
182 young
patients age
49.2 ± 27.4
Bursa,
Turkey⁴

12%48 patients
Southampt
on, UK⁵

12%
1,627
patients
from
Medicare
database⁶

11.1% 1,096 patients from STS database⁷

- Patients who require repeat mitral valve surgery often have many comorbidities and therefore a high risk of mortality.
- Several studies suggest that procedural mortality ranges from 6.3% to 15%.

¹Jamieson et al, Circulation 2003;108[suppl II]:II-98-II-102

²Albeyoglu, et al. Thorac Cardiovasc Surg 2006;54(4):244-249

³Toker et al, Tex Heart Inst J 2009; 26(6):557-562

⁴Ozyazicioglu et al, Turkish J Thorac Cardiovasc Surg 2012;20(3):497-502

⁵Vohra et al, Interact Cardiovasc Thorac Surg 2012 May;14(5):575-579

⁶Kwedar et al, Ann Thorac Surg 2017;104:1516-21

⁷Mehaffey et al, Heart 2018;104:652-656

Transcatheter mitral valve replacement: A suitable alternative?

- Registry data where many patients were treated transapically still show a rather high all-cause mortality after 30 days.
- As expected, the level of the STS score seemed to have had an impact on mortality.

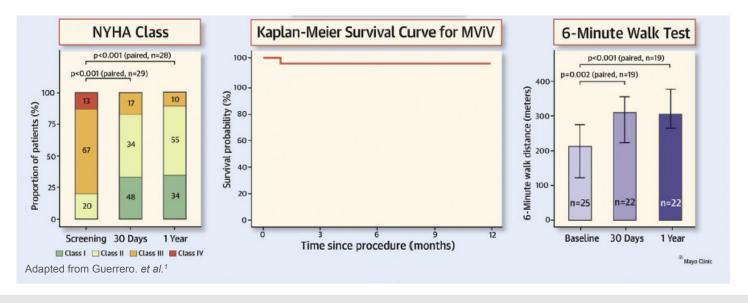
8.1%680 patients
STS 10%
TVT-Registry¹

6,5%857 patients
STS 8.6%
VIVID-Registry ²

46,8% Transapical 64.4% Transapical

¹Guerrero et al. Circ Cardiovasc Interv . 2020 Mar;13(3):e008425 ²Simonata et al. Circulation . 2021 Jan 12;143(2):104-116

Transseptal TMVR for Failed Surgical Bioprostheses



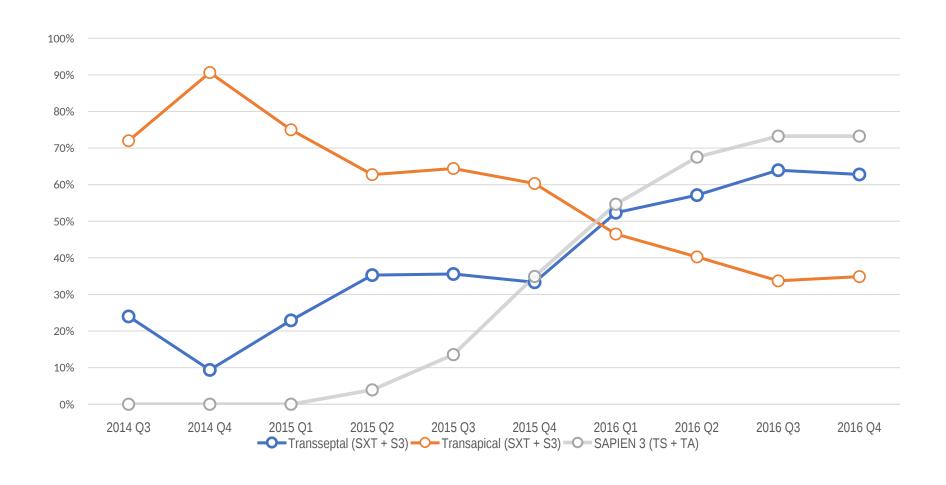
- This is the first prospective, multicenter trial assessing SAPIEN 3 outcomes in the mitral position with both imaging core labs and adjudication committee.
- In selected patients at high surgical risk (STS:9.4%): 100% technical success, low procedural complication rates, and very low mortality rate (3.3%) at 1 year.
- After procedure: alleviation of symptoms, improvement in 6-min walk distance and improvement in quality-of-life scores.

At least in selected patients requiring repeat mitral valve replacement, a transseptal approach can provide a very safe treatment option.

¹Guerrero et al, JACC Cardiovasc Interv. 2021 Apr 26;14(8):859-872



Transseptal TMVR for Failed Surgical Bioprostheses







Procedure Planning Key Points

Know the patient-specific anatomy

Know the surgical bioprostheses before the procedure

- 1. Appropriate Sizing
- 2. Correct Positioning
- 3. Evaluate Risk of LVOTo

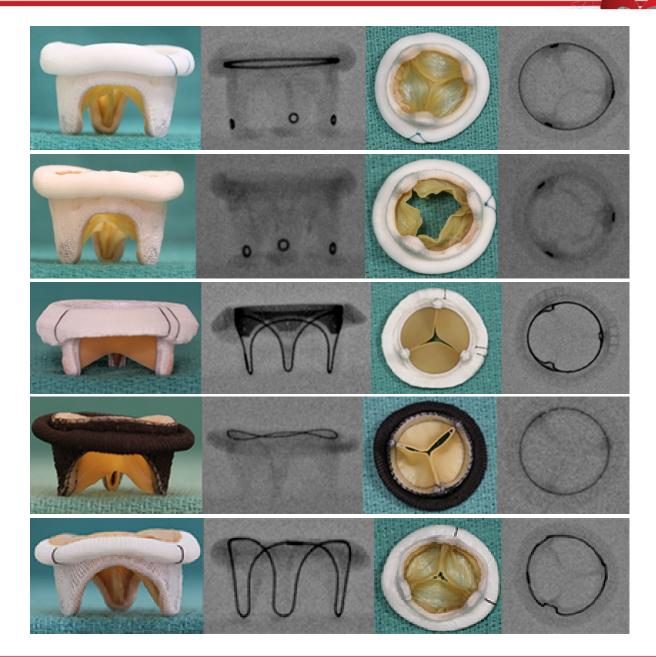
TTE Echo Evaluation Biocardiolab Ftgm bcl.ftgm.it

Know the Valve

Each valve looks different

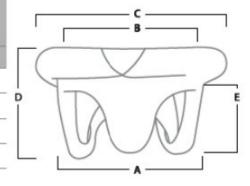
The specific model will determine:

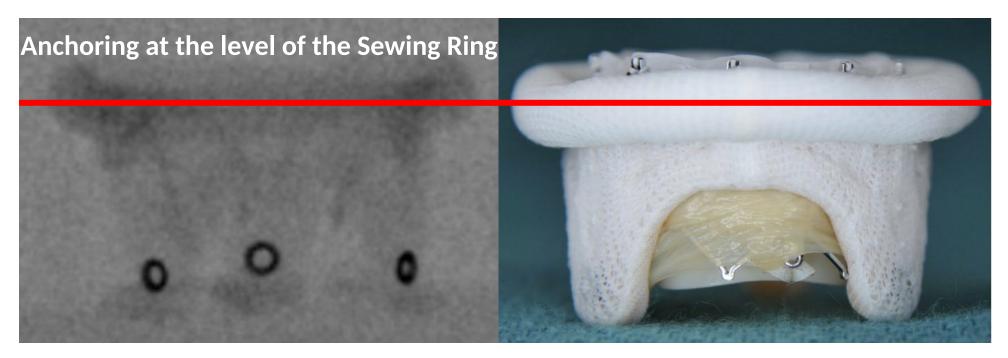
- SAPIEN 3 sizing
- SAPIEN 3 positioning
- Risk of LVOT obstruction



Know the Valve Medtronic Mosaic 29 Technical characteristics

Order Number	A Valve Size (Stent O.D.†)	B Orifice Diameter (Stent I.D.)	C Suture Ring Diameter	D Valve Height	E Ventricular Protrusion
	(±0.5mm)	(±0.5mm)	(±1mm)	(±0.5mm)	(±0.5mm)
310C25	25	22.5	33.0	18.0	13.5
310C27	27	24.0	35.0	19.0	14.0
310C29	29	26.0	38.0	20.5	15.5
310C31	31	28.0	41.0	22.0	17.0
310C33	33	30.0	43.0	23.0	17.5









Ring/band types: confusing for ViR

Complete, Incomplete, Partial





Rigid, Semi-rigid, flexible





D-shape, Circular



Uniplanar, Saddle

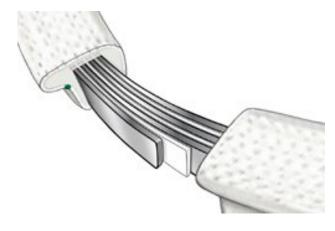








Ring Core defines ability to circularize and provide anchor





Core defines the property

Rigid: Titanium Band

Semi Rigid: Multiple Elgiloy plates/Nitinol chains, Metal and suture combination

Flexible: Suture or only silicon





Simplified classification of Rings for VIR

Complete Rigid Rings

Complete Semirigid Rings

Complete Flexible Rings Incomplete Bands & Rings Green: Suitable

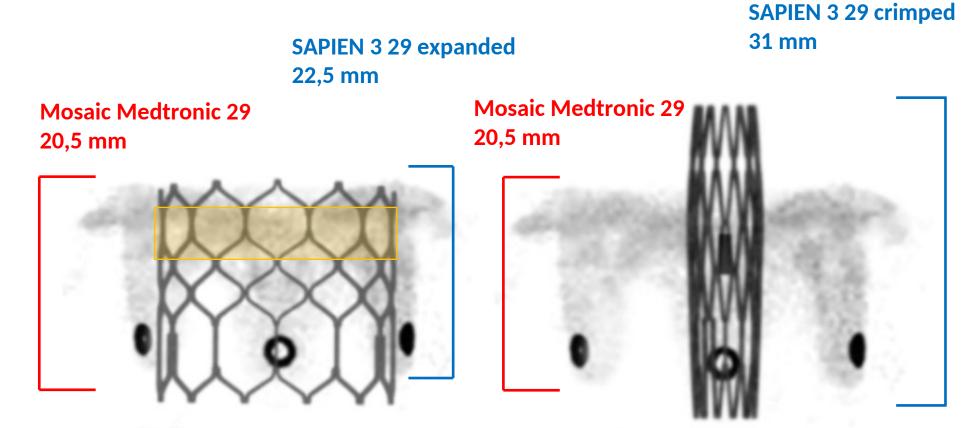
Orange: May be suitable

Red: Not suitable

Grey: Debatable!

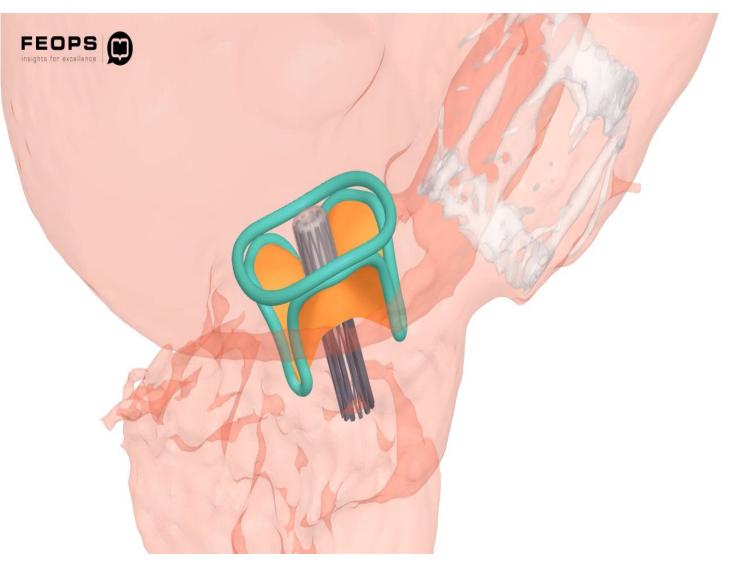
SAPIEN 3 Valve Positioning in Surgical Bioprostheses





SAPIEN 3 29 Foreshortening (crimped – expanded) = 8,5 mm

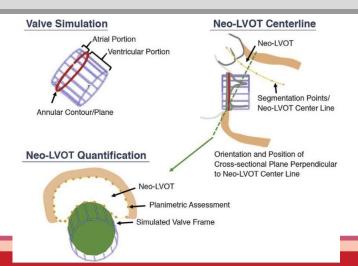
Feops Simulation Edwards Sapien 3 29

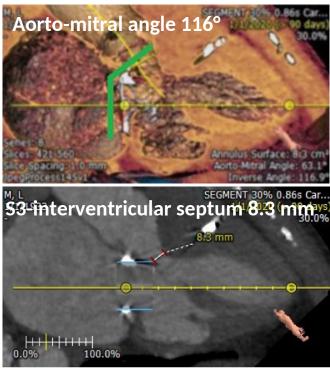




Risk Assessment of LVOT Obstruction-CT

- Distance of the prosthetic post from the IV septum
- Aorto-Mitral angle: >110 degrees is generally favorable
- Left Ventricle Anatomy
- Size and hypertrophy of LV
- Thickness or bulging of Intraventricular septum
- Neo-LVOT area >2 cm²





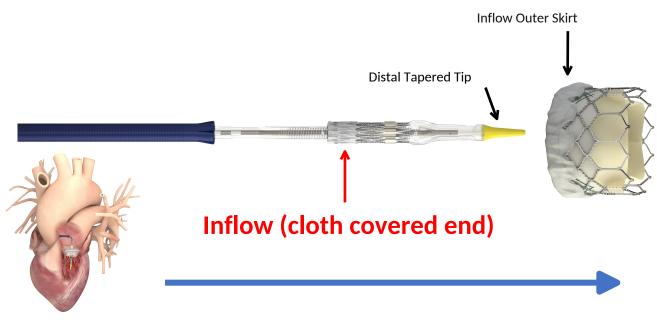


Verify SAPIEN 3 THV Orientation with Commander System for Mitral Position



Transseptal Mitral Position

Outer sealing skirt (inflow) of THV oriented proximally towards pusher and outflow end oriented towards the distal tapered tip



Blood flow direction















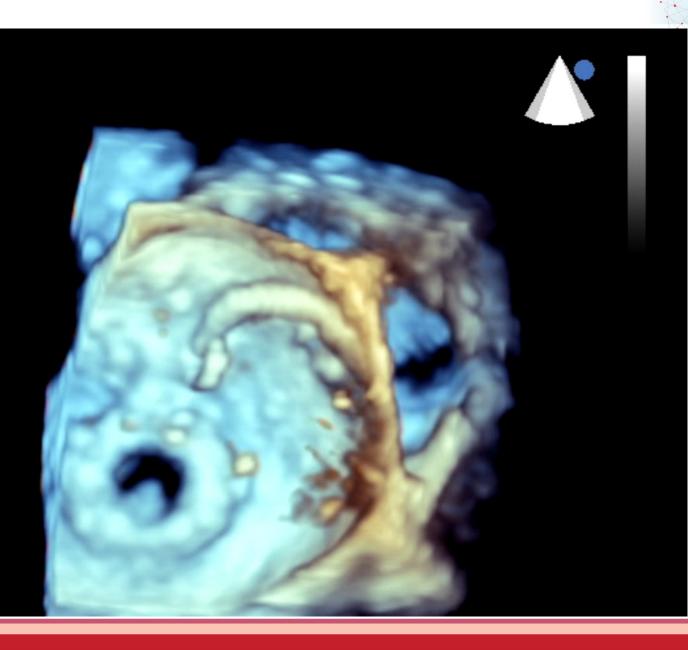




12cm

<u>3D</u> 3D 52% 3D 40dB

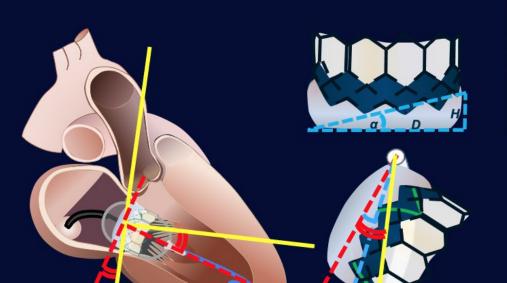


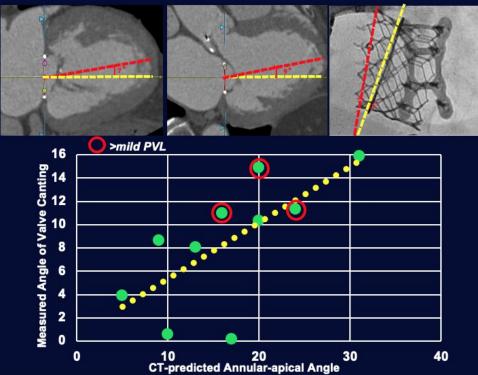




Valve alignment

The Annular to Apical "Emory" Angle







Greenbaum, et al. JACC Cardiovasc Interv 2020

Key Messages



- > A good understanding of:
 - the bioprosthesis (technology, size, fluoroscopic aspect etc.) and the previous surgical procedure
 - the anatomy of the patient
- > A good procedure planning (do not improvise):
 - Step by step
 - Identification of contraindications
 - Evaluate the risk of complications (eg. Risk of LVOT obs.)
 - Accurate sizing and positioning
- Usage of multimodality imaging (CT, TEE, Fluoro, advanced analysis)





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